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**510k Submission , SONOTRAX Ultrasonic Fetal And Vascular Pocket Doppler Edan Instruments,Inc.**

# SUMMARY

MAR 11 2008

This summary of 510k safety and effectiveness information is being submitted in Accordance with 21CFD part 807.92

1. Submitters name, address, phone number, contact person and preparation date:

Name: Edan Instruments,Inc
3/F-B ,Nanshan Medical
Equipments Park,
Nanhai Road #1019
Shekou, Nanshen, Shenzhen
518067 P.R. China
Tel: 86 755 2689 9197
Fax:86 755 2688 2223
Responsible person: Liu Yongying

Official Correspondent:

William Stern

Multigon Industries, Inc.

1 Odell Plaza

Yonkers, N.Y. 10701

Phone: 914 376 5200 x27
Fax: 914376 6111

Date of Preparation: 1/9/08

2. Device:

Proprietary Name: Sontotrax Ultrasonic Fetal and Vascular Pocket Doppler Models: Sonotrax Lite, Sonotrax Basic,

Sonotrax Basic A, Sonotrax Pro, Sonotrax II, Sonotrax II Pro,

Sonotrax Vascular

SONOTRAX 510K SUBMISSION

Common Name: Handheld Fetal and Peripheral Vascular Doppler

Classification name: Fetal Ultrasonic Monitor and Accessories
Ultrasonic Bloodflow Monitor
Diagnostic ultrasonic transducer

Product Code: KNG
HEP

Manufactured By: Edan Instruments, Inc., China

3. Predicate Devices:

K040480 Sonotrax Ultrasonic Pocket Doppler, manufactured by Edan Instruments, Inc.

K024197 LifeDop Doppler Ultrasound System , manufactured by Summit Doppler Systems,

5350 Vivian St., Suite A, Arvada, CO 80002

4. Classification Names :

Class II as per 21CFR 884-2660, Fetal Ultrasonic Monitor and accessories.(KNG)

Class II as per 21CFR 884-2660, Ultrasonic Bloodflow Monitor (HEP)

5. Description:

The Sonotrax fetal Dopplers enumerated in their various models in 2. above use the tried and true principle of Doppler shift of an ultrasound signal to detect the fetal heartbeat using the 2 mHz and or 3 mHz probes and for blood flow detection in veins and arteries using the 4 mHz and 8 mHz probes.

The Sonotrax Fetal Dopplers uses a split D piezoelectric transducer. A high frequency oscillator supplies a continuous high frequency voltage to one half of the split D transmitter transducer. The high frequency voltage is converted to an ultrasound acoustic wave by the transducer and is transmitted to biophysical objects thru an applied coupling water based medium and moves thru biophysical objects. The acoustic ultrasound is

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reflected by moving blood cells and moving objects such as the fetal heart. The reflected ultrasound is received by the second split D receiver transducer and is converted via the piezoelectric effect into a high frequency electronic signal. The received electronic signal is amplified and detected. The result is a base band audio Doppler shifted signal which is filtered , and converted to audio via a loud speaker. At the same time the fetal heart rate is applied to and displayed on a liquid crystal counter display.

The Sonotrax product includes four interchangeable probes (2mHz and 3 mHz Obstetrical probes and 4mHz and 8mHz vascular probes).

The user interface includes an on/off button, a play /record button (only in the Sonotrax Pro model), a loud speaker, headphone jack, LCD display for heartrate (all models except Sonotrax lite), and a battery.

6. Indications for use:

The 2 mHz and/ or 3 mHz obstetrical probes are indicated for the detection of fetal life .from early gestation thru delivery and as a general indication of fetal well being. They can also be used to verify fetal heart viability following patient trauma.

The 4 mHz and/ or 8 mHz vascular probes are indicated for the detection of blood flow in veins and arteries for assisting in the detection of peripheral vascular disease.

The Sonotrax series of pocket dopplers are to be used by health care professionals including registered nurses, practical nurses, midwives, ultrasound technicians, and physicians assistants, by prescription from licensed physicians in hospitals, clinics and private offices.

7. Contraindications: None known at this time.

Comparison to Predicate Device.

The Sonotrax Ultrasonic Fetal and Vascular Pocket Doppler models in 2. above including the Lite, Basic,Pro, II, and Vascular models have the same device characteristics as all the predicate approved devices in item 3 above.All of these above models use the same technology and circuitry as the already approved Sonotrax Doppler cleared under K040480. In this application we have added a 3 mHz probe frequency for fetal use , and a 4 mHz and 8 mHz vascular probes for vascular use. These Sonotrax models are also similar and comparable to the Lifedop Doppler cleared under K024197. Hence the Sonotrax Fetal and Vascular Pocket Doppler models in paragraph 2 above are substantially equivalent to the predicate devices cited.

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9. Test Data:

The Sonotrax Ultrasonic Fetal and Vascular Doppler devices have been designed under design control procedures in the company's QSR system as enumerated in the Cerctificate of Conformance and subjected to extensive safety, performance testing and validations before release. Final testing of the Sonotrax Ultrasonic Fetal and Vascular Dopplers includes various performance tests designed to ensure that the device meets all of its functional requirements and performance specifications. Safety tests have further been performed to ensure the device complies with applicable industry and safety standards.

The Sonotrax Ultrasonic Fetal and Vascular Doppler device labeling includes instructions for safe and effective use, warnings cautions and guidance for use.

10. Literature Review:

A review of the literature pertaining to the safety of Doppler Blood flowmeters has been conducted and appropriate safeguards have been incorporated in the design of the Sonotrax Ultrasonic Fetal and Vascular Fetal Dopplers.

10. Conclusions:

The conclusion drawn from these tests is that the Sonotrax Ultrasonic Fetal and Vascular Dopplers described herein are equivalent in safety and efficacy to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 1 2008

Edan Instruments, Inc.
c/o Mr. William Stern
Official Correspondent
Multigon Industries, Inc.
1 Odell Plaza
YONKERS NY 10701

Re: K080087
Trade/Device Name: Sonotrax Ultrasonic Fetal and Vascular Pocket Doppler
Regulation Number: 21 CFR §884.2660
Regulation Name: Fetal ultrasonic monitor and accessories
Regulatory Class: II
Product Code: KNG
Dated: January 9, 2008
Received: January 23, 2008

Dear Mr. Stern:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Sonotrax Ultrasonic Fetal and Vascular Pocket Doppler, as described in your premarket notification:

Transducer Model Number

| | |
|---|---|
| 8 mHz CW Vascular Probe | 4 mHz CW Vascular Probe |
| 3 mHz CW Fetal Probe | 2 mHz CW Fetal Probe |

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Gamal Akabani, Ph.D. at (240) 276-3666.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

# Indication for Use

510(k) Number (if known):

Device Name: Sonotrax Ultrasonic Fetal and Vascular Pocket Doppler

Indication for Use:

The 2 mHz and/ or 3 mHz obstetrical probes are indicated for the detection of fetal life from early gestation thru delivery. They can also be used to verify fetal heart viability.

The 4 mHz and/ or 8 mHz vascular probes are indicated for the detection of blood flow in veins and arteries for assisting in the detection of peripheral vascular disease.

The Sonotrax series of pocket dopplers are to be used by health care professionals including registered nurses, practical nurses, midwives, ultrasound technicians, and physicians assistants, by prescription from licensed physicians in hospitals, clinics and private offices.

The model includes Sonotrax Lite, Sonotrax Basic, Sonotrax Pro, Sonotrax Basic A, Sonotrax II, Sonotrax II Pro, Sonotrax Vascular.

Prescription Use ___Yes___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _No_. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K080087

Appendix F

## Diagnostic Ultrasound Indications for Use Form

**Fill out one form for each ultrasound system and each transducer.**

3 mHz CW FETAL PROBE- MODEL: SONOTRAX

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | N | | | | | |
| Abdominal | | | | | | | | | | |
| Intraoperative (specify) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (specify) | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: The above is a 3 mHz CW transducer for FETAL HEART RATE DETECTION MODEL CD3.0-MS3

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K080087

Appendix F

## Diagnostic Ultrasound Indications for Use Form

**Fill out one form for each ultrasound system and each transducer.**

8 mHz CW VASCLR PROBE- MODEL: SONOTRAX

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intraoperative (specify) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (specify) | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | | | | N | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: The above is a 8 mHz CW transducer for detection of blood flow in veins and arteries MODEL CD8.0-MS3

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K080087

Appendix F

## Diagnostic Ultrasound Indications for Use Form

**Fill out one form for each ultrasound system and each transducer.**

4 mHz CW VASC. PROBE- MODEL: SONOTRAX

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intraoperative (specify) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (specify) | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | | | | N | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: The above is a 4 mHz CW transducer for DETECTION OF BLOOD FLOW IN VEINS AND ARTERIES MODEL CD4.0-MS3

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K080087

Appendix F

continious wave doppler (CWD)

## Diagnostic Ultrasound Indications for Use Form

**Fill out one form for each ultrasound system and each transducer.**

2 mHz CW FETAL PROBE- MODEL: SONOTRAX

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | P | | | | | |
| Abdominal | | | | | | | | | | |
| Intraoperative (specify) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (specify) | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: The above is a 2 mHz CW transducer for fetal heart rate detection. MODEL CD2.0-MS3

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, **Abdominal,** and Radiological Devices

510(k) Number K080087